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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/[illegible]21	11/20/98	SIN Y	1459-005D

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EXAMINER	
MINNIFIELD,N	
ART UNIT	**PAPER NUMBER**
1645	22

DATE MAILED: 03/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/196,161	Applicant(s) SIN ET AL
	Examiner N. M. Minnifi Id	Group Art Unit 1645

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-23 is/are pending in the applicat

Of the above, claim(s) 9-23 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-8 is/are rejected.

☒ Claim(s) 5 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892 6 sheets

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☒ Interview Summary, PTO-413 (9-14-00; 2-1-01)

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's election of Group I, claims 1-8, in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP. § 818.03(a)).

2. Claims 9-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

3. The disclosure is objected to because of the following informalities: There are no figures/drawings in the application although the specification contains a section entitled "BRIEF DESCRIPTION OF THE DRAWING" (see p. 7, figures 1A, 1B, 1C, 2A, 2B). The transmittal letter with the originally filed application on November 11, 1998 does not indicate that any figures were submitted. The figure descriptions on p. 7 and any references to the figures should be deleted from the specification (see also pp. 8-10, 15, and 16). Appropriate correction is required.

4. The amendment filed September 15, 2000 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the

invention. The added material which is not supported by the original disclosure is as follows: SEQ ID NO: 19. The primer sequence on page 11 is 17 base pairs long, which is the same as SEQ ID NO:17 in the RAW SEQUENCE LISTING and CRF filed November 19, 2000. The RAW SEQUENCE LISTING and CRF filed November 19, 2000 does not have a SEQ ID NO:19; the CRF has 17 sequences. Further, Applicant is correct that p. 20 has 3 sequences but the examiner finds no "drawing originally submitted contained 9 sequence listing". With regard to the current sequence listing Applicant should indicate how sequences derived from original to show support for current SEQ ID NOs.

Applicant is required to cancel the new matter in the reply to this Office action.

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 3 recites a "substantially inert medium".

6. Claims 3, 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7 and 8 recite the limitation "ciliated protozoan" in the claim. There is insufficient antecedent basis

for this limitation in the claim. Claim 3 is vague and indefinite in the recitation of "substantially inert medium"; what are the metes and bounds of substantially?

7. Claim 5 is objected to because of the following informalities: there is period in the middle of the claim and there is no period at the end of the claim. Appropriate correction is required.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-7 are rejected under 35 U.S.C. 102(a) or (b) as being anticipated by He et al (1997).

The claims are directed to a vaccine comprising a recombinant fusion protein, GST-iAgI, and substantially inert medium (buffer, adjuvant, immunostimulant, or carrier).

He et al disclose a recombinant fusion protein, GST-iAgI (abstract). He et al disclose that the fusion protein was expressed in *E. coli* and that "the recombinant GST-iAgI fusion protein can be used as a potential vaccine against the infection of *I. multifiliis*" (abstract). The prior art uses an adjuvant (FCA) in the vaccine composition (p. 5). The vaccine is used to protect against white spot disease in fish caused by *Ichthyophthirius multifiliis*, a ciliated protozoan parasite (p. 1). The prior art anticipates the claimed invention.

13. Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over He et al taken with Clark et al (1992).

He et al teach a recombinant fusion protein, GST-iAgI (abstract). He et al teach that the fusion protein was expressed in *E. coli* and that "the recombinant GST-iAgI fusion protein can be used as a potential vaccine against the infection of *I. multifiliis*" (abstract). The prior art uses an adjuvant (FCA) in the vaccine composition (p. 5). The vaccine is used to protect against white spot disease in fish caused by *Ichthyophthirius multifiliis*, a ciliated protozoan parasite (p. 1). The prior art teaches the claimed invention except for the ciliated protozoan are taxonomically related to *Ichthyophthirius multifiliis*.

However, Clark et al teach that the I-antigens of *Ichthyophthirius multifiliis* can be used in the development of protective immunity in fish (p. 6363). Clark et al teach that "...the common fish parasite *Ichthyophthirius multifiliis (Ich)* represents a bridge between the free-living ciliates and parasitic protozoa. As a holotrich ciliate, it is taxonomically related to both *Paramecium* and *Tetrahymena* (order Hymenostomatida) and... has I-antigens directly analogous to those found on the free living ciliates." (p. 6363, col. 2). It would have been obvious to a person of ordinary skill in the art at the time the invention was made at to use the vaccine of He et al comprising the recombinant fusion protein (GST-iAgI) and adjuvant with a reasonable expectation of protecting against infection of other taxonomically related ciliated protozoan as set forth in Clark et al. Clark et al teach that other taxonomically related ciliated protozoan have the I-antigen (immobilization antigens). The claimed invention is prima facie obvious in view of the prior art absent any convincing evidence to the contrary.

14. No claims are allowed.

15. The information disclosure statement filed February 23, 1999 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed

in the application file, but the information referred to therein has not been considered.

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is (703) 305-3394. The examiner can normally be reached on Monday-Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R. F. Smith, can be reached on (703) 308-3909. The fax phone number for Technology Center 1600 is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

NITA MINNIFIELD
PRIMARY EXAMINER

N. M. Minnifield

March 25, 2001